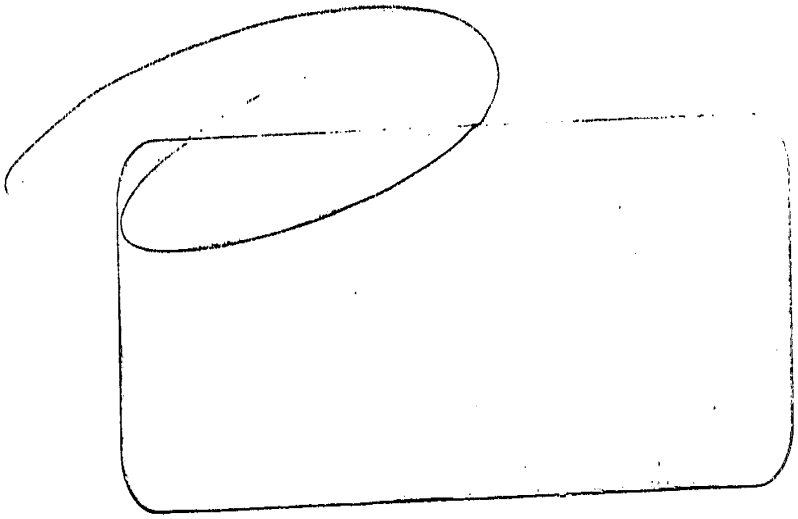
Organization TC1600 Bldg/Room REMSEN

United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
If Undeliverable Return in Ten Days

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

AN EQUAL OPPORTUNITY EMPLOYER

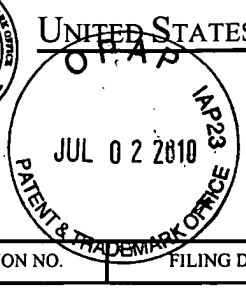
UNITED STATES POSTAGE
PITNEY BOWES
02 1M $ 01.39⁰
0004244939 JUN 28 2010
MAILED FROM ZIP CODE 22314



WEND033+ 200062021 1209 21 07/01/10
FORWARD TIME EXP RTN TO SEND
:WENDEROTH LIND & PONACK LLP
1030 15TH ST NW STE 400E
WASHINGTON DC 20005-1500

RETURN TO SENDER

UNITED STATES PATENT AND TRADEMARK OFFICE



IAW

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,168	09/10/1999	TOSHIMITSU ISHIKAWA	724-P10-2589	2333

7590 06/28/2010

WENDEROTH LIND & PONACK LLP
2033 K STREET NW
SUITE 800
WASHINGTON, DC 20006

EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
06/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/393,168	ISHIKAWA ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/19/10*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9-11,13-15 and 17-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9-11,13-15 and 17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/19/10 has been entered.

Receipt is acknowledged of the Amendments and Remarks filed on 04/19/10. Claims 1, 19 and 20 have been amended, claims 5-8, 12 and 16 have been cancelled and no new claims have been added. Accordingly, claims **1-4, 9-11, 13-15 and 17-22** remain pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure lacks any written description

for "soft extract material" and one of ordinary skill in the art would not be able to determine what is meant by a soft extract material.

The instant invention is directed to soft extract materials with no disclosure on what they are or what their intended use is. The specification does not indicate what particular components are found in those extracts or how they are obtained. The specification also does not indicate what is meant by "soft".

The term extracts does not meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are or composed of. The specification provides insufficient written description to support the genus encompassed by the claim. Note: MPEP 2163.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:
The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

The skilled artisan cannot envision the detailed chemical structure of the encompassed soft extract materials, regardless of the complexity or simplicity of the method of isolation or preparation. **Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.** The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Circ. 1993) and Amgen Inc. V. Chugai Pharmaceutical

Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991). In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (Bd. Pat. App. & Int. 1993), claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing **"sufficiently detailed, relevant identifying characteristics,"** including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

Therefore the instant claims do not meet the written description provision of 35 USC § 112, first paragraph. The chemical species encompassed by the word extract results in a genus that is highly variant as different isolation methods can lead to isolation of different species and applicant has not indicated what identifying characteristics are associated with the extracts. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "substantially free" in claims 1-4, 9-11, 13-16, 17-22 is a relative term which renders the claim indefinite. The term "substantially free" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no definition of the term "substantially free" with regards to dispersion stabilizer or fat and oil material or oil-soluble material. The definition of "substantially free" on page 5 is for emulsifying agent only.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 9-11, 13-15 and 17-22 are **rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al (5,569,466) in view of Miskel et al (3,851,051).**

Tanner et al teach **fill compositions for soft gel capsules** comprising an active agent dissolved or **suspended** in a carrier liquid (see abstract). Example 2 discloses a process of preparing a suspension wherein the **liquid** mixture is **homogenized** using high shear mixing techniques (see col. 4, lines 63-67). Examples 1, 2, 5, 6 and 8 disclose a fill composition comprising active agents and maltitol syrup (or lycasin) (a polysaccharide). No dispersion stabilizers, oil or fats are included. Examples 4 and 7 disclose fill compositions comprising active agents, maltitol syrup and peppermint oil. No dispersion stabilizers included. Tanner et al teach fill formulations comprising a polysaccharide such as lycasin, however does not specifically teach adding a dietary fiber. Tanner et al also lacks disclosure on adding fats and oils. These deficiencies are cured by Miskel et al.

Miskel et al teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited oil solubility (diphenhydramine) (see Example 1). Further, Miskel et al teach a soft capsule comprising a **water-soluble dietary fiber** (apple pectin), a material of limited oil soubility (glycerin) and a fat and oil material or oil soluble material (vitamin E) (see Example 50). In Example 43, Miskel et al teach a soft capsule comprising a **water-soluble dietary fiber** (citrus pectin) and a material of

limited oil solubility (sodium saccharine). No dispersion stabilizer and fat and oil material or oil soluble material is present. High stability is disclosed (column 1, line 18-25).

Miskel et al provide a **stable soft gelatin capsule** having a water containing solution or **suspension** of an active ingredient **in the fill** (see col. 3, lines 41-44).

Miskel et al provide a soft gelatin capsule having a fill containing as high as a15-20% water solution of an active ingredient, yet which has a long life and does not exhibit the problems of softening, deterioration, or attack by substances normally deleterious to the gelatin shell (see col. 3, lines 53-58).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the soft capsule formulations of Tanner et al, to have looked in the art for other ingredients such as water-soluble dietary fibers for the fill composition, as disclosed in Miskel et al with a reasonable expectation of successfully preparing a stable homogenized fill composition for soft capsules. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and **the combination would have yielded predictable results** to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Applicant's arguments filed 04/19/10 have been fully considered but they are not persuasive. Applicant takes the position that Examiner has not satisfied the

requirements for establishing a presumption of obviousness. Applicant argues that "In the soft capsule (finished product) of Miskel et al. the active medicinal ingredient is contained in a macromolecular gel-lattice matrix that is a rigid gel system of pectin (dietary fiber) or the like that has been set by cooling and drying. Thus, the state of the active medicinal ingredient and the function of the pectin (dietary fiber) of Miskel et al. are clearly different from those in the soft capsule of the present invention, in which the active medicinal ingredient: is a suspension of a liquid type and the dietary fiber functions to stabilize the suspension of a liquid type in the finished soft capsule". This is not persuasive because 1) the instant claims do not exclude a matrix, 2) the reference is relied upon the compositions of Miskel before the cooling and drying takes place and rigid gel is formed 3) the argument of "dietary fiber functions to stabilize the suspension" is considered an intended use limitation and not given weight in a formulation claim. It has been shown that the combination of references would result in a product that comprises all the components of the claimed product.

Applicant then argues that "in the method of Miskel et al., the pectin (dietary fiber) is used for forming a macromolecular gel-lattice matrix (vehicle) that acts as a carrier for the active ingredient and that does not destroy the capsule shell. In the soft capsule of Tanner et al a maltitol syrup is also used as a carrier to dissolve or suspend active ingredients, which syrup provides stability for the fill material and is compatible with the SEG (soft elastic gelatin) shell". Applicant then concludes that one of ordinary skill in the art would not have been motivated to combine the two references and that "Accordingly, the teachings of Miskel et al. and Tanner et al. do not suggest the present

invention". This is not persuasive because Tanner teaches the capsules and the fill composition. Miskel also teaches a homogenized liquid fill composition comprising the dietary fiber and an oil compound. One of ordinary skill in the art would have been motivated to include the fiber and the oil component of Miskel because of their benefit to the patient and treatment effect. In other words, it would have been obvious to one of ordinary skill in the art to have included the pectin (dietary fibers) of Miskel in the soft capsules of Tanner et al. Obviousness comes from either the references themselves or the knowledge available to one of ordinary skill in the art. Here, it has been shown that Tanner et al discloses the general formulations and one of ordinary skill in the art could have looked in the art for specific species, and as well, one of ordinary skill in the art knows that the soft capsules can contain almost any active agent. It is a general delivery vehicle.

Applicant also argues that "Furthermore, even if a prima facie case of obviousness had been established, it would be overcome by the showing of unexpected superior results achieved in accordance with the present invention, attention in this regard being directed to a comparison between Example 1 and Comparative Example 1 on pages 8-11 of the present specification. As clearly shown by Table 1 on page 10, the composition of Example 1, which includes the dietary fiber, permits the raw royal jelly to be contained in a much higher amount (60%) as compared to the amount of raw royal jelly (30%) achieved by the composition of Comparative Example 1 which does not contain the dietary fiber. As also shown by Table 1, the present invention permits the suspended stock solution with increased suspension stability to be prepared without

incorporating any fat and oil material, and any suspension stabilizer (see amended claims 1, 19 and 20); and permits the suspended stock solution to be encapsulated in the soft capsule with significantly increased stability with time and quality".

This is not persuasive because the unexpected results Applicant is relying on (Data in Table 1 of the specification) are not sufficient to overcome the rejection. Firstly it is noted that the term "substantially free" is not defined by the specification with regards to stabilizer and fats and oils or oil-soluble material. Even if one was to expand the definition of "substantially free" given on page 5 for emulsifying agent, it states that in one case "it contains the agent in a concentration substantially decreased as compared with the conventional soft capsule". The definition itself is relative and sets no standard of ascertaining the requisite degree. Additionally, specification does not provide an adequate list of dispersion stabilizers and one of ordinary skill in the art would not be able to determine which components are considered stabilizers and what components are meant to be excluded. It is known in the composition art that certain additives have multiple functions. Additives such as surface active agents, antioxidants, emulsifiers, oils, etc can also function as stabilizers. Claims use the open language of comprising and "consisting essentially of". Furthermore, claims 1-4 do not include or exclude fats and oils or oil-soluble materials, whereas claims 9-11 attempt to exclude fats and oils or oil-soluble materials. Claims 13-15 and 17-22 actually require fats and oils or oil-soluble materials in varying amounts. Now, interpreting the data that Applicant considers unexpected results, it is not apparent what component gives formulation of Example 1, its "good" stability and "good" workability. The comparison

between composition 1 and comparative composition 1 in Table 1, shows that composition 1 contains no fats and oil material and no dispersion stabilizer, while comparative composition 1 does. In table 2, however, the formulation contains oils and fats and shows "good" stability and workability. The two formulations also show "no separation". Thus Applicants argument that "suspended stock solution with increased suspension stability to be prepared without incorporating any fat and oil material" is not supported. It is also noted that neither references relied upon teach formulations comprising the dispersion stabilizers cited by the specification or employed in the comparative Example.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-4, 9-11, 13-15 and 17-22 remain rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616